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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,057	02/05/2001	Colin Brown	9052-67	1282
20792 7590 07/16/2007 MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627				
			EXAMINER WHITE, EVERETT NMN	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 07/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

09/700,057

Applicant(s)

BROWN, COLIN

Examiner

Everett White

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23,26-35 and 45-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23,26-35 and 45-83 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>May 18, 2007</u> . | 6) <input type="checkbox"/> Other: _____  |

Art Unit: 1623

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 18, 2007 has been entered.
2. The amendment filed May 18, 2007 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
  - (A) Claims 1-22, 24, 25 and 36-44 were previously canceled;
  - (B) New Claims 52-83 have been added;
  - (C) Claims 23, 27-29, 31, 45, 46 and 51 have been amended;
  - (D) Comments regarding Office Action have been provided drawn to:
    - (I) 103(a) rejection, rendered moot by new ground of rejection over a newly cited reference.
3. Claims 23, 26-35 and 45-83 are pending in the case.

### ***Claim Rejections - 35 USC § 103***

#### ***New Grounds of Rejection***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1623

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 23, 26-35 and 45-83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dobbie ("Separation of Peritoneal Surfaces Through the Maintenance of an Artificial Ascites as a Preventative of Peritoneal Adhesions" Abstract, from The 4th Peritoneum and Peritoneal Access Meeting, September 16-19, 1997, already of record) in view of Milner (US Patent No. 4,886,789, already of record) or Treutner et al (Journal of Surgical Research, "Prevention of Postoperative Adhesions by Singly Intraperitoneal Medication", Vol. 59, pages 764-771 (1995), newly cited).

Applicant claims a method of reducing the incidence of post-operative adhesions in a body cavity, comprising introducing into the body cavity a composition comprising an aqueous formulation further comprising a polysaccharide dextrin in an amount effective to reduce the incidence of said post-operative adhesions, wherein the dextrin is unsubstituted and the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12 and acts as an osmotic agent to maintain a volume of the aqueous formulation in the body cavity serving to separate tissues which otherwise may adhere to each other, and wherein the aqueous formulation is a solution in the body cavity and further remains in the body cavity for at least 2 days.

The abstract of the Dobbie reference discloses development of Icodextrin (glucose polymer) as a non-glycating, long-dwell, peritoneal solution of physiological osmolarity for use in peritoneal dialysis as a dialysate, a carrier solution for continuous ambulatory chemotherapy, and for use post-operatively in patients with a high risk of abdominal adhesions. This statement embraces the general description of the instantly claimed method of reducing the incidence of adhesions in a body cavity since the terms Icodextrin and non-glycating; peritoneal & abdominal; post-operatively; and long-dwell all suggest the dextrin, body cavity, unsubstituted dextrin, post-operative and the period of time disclosed in the instant claims.

The instantly claimed method of reducing the incidence of adhesion in a body cavity differs from the separation of peritoneal surfaces described in Dobbie reference by claiming that the dextrin contains more than 15% of polymers with a degree of polymerization (DP) greater than 12.

However, the Milner patent shows that dextrin having 15% polymers with a degree of polymerization greater than 12 is well known in the art. The Milner patent discloses a peritoneal dialysis composition containing an osmotic agent comprising a glucose polymer mixture, said mixture including at least 15% by weight of glucose polymers having a DP greater than 12 (see abstract). See column 6, line 39 and 43, wherein preparation of the glucose polymer mixture is described and wherein the term dextrinised starch is mention, which suggest that the glucose polymer mixture of the Milner patent is dextrin. Also see column 9, line 9, wherein the Milner patent describes a typical peritoneal dialysis solution as comprising 2 to 15% w/v of glucose polymer, which falls within the amount of concentrated dextrin that may be applied to a body cavity disclosed in instant Claims 32-34, 65, 75 and 82. See column 11, lines 22-24 wherein the Milner patent describes an infusion of peritoneal dialysis solutions being 2 liters in volume, wherein a total amount of infusion may be 6 liters per day, which embraces the volume of the amount of the composition disclosed in instant Claims 30, 31, 63, 64, 73 and 74.

The Treutner et al reference is cited to further show that the use of products in the prevention of postoperative adhesions for abdominal, gynecological and cardia surgery is known in the art (see title and abstract). The Treutner et al reference teaches the administration of various types of products post-operatively in a single application, wherein the products remain for an extended period of time as disclosed in instant Claims 23, 27, 29, 45, 62, 72 and 81. The amount of the substances used in the Treutner et al reference (a volume of 1 ml per 100 g body wt.) embraces the amount of the composition used in instant Claims 30, 31, 63, 64, 73 and 74 (see page 765, 1<sup>st</sup> column, 2<sup>nd</sup> paragraph and the 2<sup>nd</sup> paragraph in the 2<sup>nd</sup> column of the Treutner et al reference).

One of ordinary skill in this art would be motivated to combine the teachings of the Dobbie reference with the Milner patent or the Treutner et al reference since the references disclose the application of a dextrin solution to the peritoneal cavity or the prevention of postoperative adhesion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the dextrin used to reduce the incidence of adhesion in a body cavity of the Dobbie reference with dextrin having 15% polymers with a degree of polymerization greater than 12 in view of the recognition in the art, as evidenced by Milner patent, that dextrin having 15% polymers with a degree of polymerization greater than 12 are more effective as osmotic agents than would be indicated by calculation based on the standard assumption that each molecule of such a polymer would be osmotically the equivalent of one molecule of dextrose or any other compound.

It also would have been obvious to substitute the Icodextrin used in the general technique of preventing post-operative adhesion of the Dobbie reference for the other substances used in the postoperative adhesion prevention procedure described in the Treutner et al reference in view of the recognition in the art, as evidenced by the Treutner et al reference, that the prevention of postoperative adhesions can be accomplished by a single intraperitoneal medication.

#### **Declaration under 37 C.F.R. § 1.132**

6. The Declaration under 37 C.F.R. § 1.132 of Elizabeth Peers, PhD, was carefully considered but was not found persuasive. The Dobbie reference is not limited to the prevention of adhesions using a continuous peritoneal dialysis procedure. The next to last sentence states: "The IBPR has since 1984 advocated the development of glucose polymer (Icodextrin) as **[1st suggested use]** a non-glycating, long-dwell, peritoneal solution ... for use in peritoneal dialysis ... **[2nd suggested use]** a carrier solution for continuous ambulatory chemotherapy; **[3rd suggested use]** and for use **post-operatively** in patients with a high risk of abdominal adhesions."

Art Unit: 1623

**\*Note that in the 2nd suggested use, continuous chemotherapy, the solution is NOT removed, contra to dialysis.**

The Dobbie reference suggests the use of the product for the prevention of post-surgical adhesions, *based on what is known from its use in peritoneal dialysis*. One of ordinary skill would use the product in the same way that other anti-adhesion products are used, not in a dialysis procedure. See, for example, Treutner et al (J. Surg. Res., 1995), cited in the rejection above. This reference discloses a general method for the instillation of anti-adhesion products during surgery. The products are instilled and remain. They are not removed. The rejection of the claims under 35 U.S.C. 103 is maintained for the reasons of record.

#### ***Summary***

7. All the pending claims (Claims 23, 26-35 and 45-83) are rejected.

#### ***Examiner's Telephone Number, Fax Number, and Other Information***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-066127. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



E. White



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